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MARKED-UP COPY OF SUBSTITUTE SPECIFICATION

DESCRIPTIONMETHOD FOR DETERMINING SLEEP STAGES

[0001] This Application is the U.S. National Stage of PCT/JP2005/003412, filed February 23, 2005, which claims priority from JP 2004-056538, filed March 1, 2004, the disclosures of which are incorporated herein in their entireties by reference thereto.

BACKGROUNDTechnical Field

[0002] The present invention relates to a method for determining sleep stages of an examinee, which determines the sleep stage from biosignals detected by a biosignal detector, detection means, and the method for determining sleep stages, which is readily handled and can be routinely used.

Background Art

[0003] When the health condition of an individual is checked, a A sleep state is often examined as an indicator for determining the health condition of an individual. It has been is well-known that sleep and health are closely associated. Health and sleep depth and quality of sleep in during the night are closely associated with mood and vigor on the following day. Meanwhile, when having during periods of mental stress or falling ill, sickness, comfortable sleep is not obtained because the depth of sleep and the transition pattern of sleep stages are changed.

[0004] In During healthy sleep, non-REM sleep and REM sleep repeatedly appear at a constant interval after falling asleep. It has been known that sleep rhythm is disturbed when falling ill or having during periods of sickness or mental stress. Therefore, it becomes possible to know the mental stress level and poor physical condition of examinees by monitoring sleep stages and their occurrence pattern during sleep during the night while the examinees sleep.

[0005] In particular, the elderly often complain of a sleep state disorder such as shallow sleep, and have a problem in sleep quality. By examining the transition of sleep

stages to understand sleep quality, it becomes possible to find ways of addressing the problem in sleep quality, and find or-measures to improve sleep quality.

[0006] As a conventional method for examining sleep stages, is a the method using a sleep polysomnogram (PSG)-is common. In the method using PSG, a significant amount of information can be obtained by estimating the activity of the cerebral nervous system during sleep from brain waves, myoelectric potential and eye movements. However, it is difficult to obtain natural sleep because the measurement is performed by mounting many electrodes on the face and the body of an examinee, and a period of several days to a week is required for growing accustomed to this method. Therefore, physical and bodily loads given to the examinee are extremely heavy, and further, it is necessary that this measurement is performed in a special facility such as a hospital by an expert who is familiarized with the handling. Therefore, the cost required for this method becomes expensive.

[0007] Due to these circumstances, though-although it can be an effective therapy to use PSG for patients with an obvious sleep disorder, it is difficult to use PSG for routine health care.

[0008] Thus, methods for simply examining sleep stages without using PSG for examining the daily health state of the examinee have been proposed. For example, the-a method for determining the sleep stages by wearing a wristwatch type vibration strength measurement device on an arm and measuring its acceleration is available, but only two stages of sleep stages, e.g., REM sleep and non-REM sleep can be detected. For health care use, however, it is necessary to detect at least three stages, i.e., the awake/REM sleep stage, the shallow non-REM sleep stage and the deep non-REM sleep stage, -and it. Thus, because this type of non-PSG device only detects two sleep stages, it is not suitable unsuitable that this device is used for purposes of health care.

[0009] The present inventor has proposed Another proposed method for determining sleep stages is a method for non-invasively measuring a heartbeat rate, and determining sleep stages from these the measured heartbeat rate signal data (e.g., see Japanese Published Unexamined Patent Application 2000-325315). This method is capable of examining-and in this method, four stages of sleep stages, e.g., the awake state, REM sleep, shallow non-REM sleep and deep non-REM sleep can be examined. Therefore, it is possible to use this method for health care. However, complicated calculations, calculation time and large memory are required because the sleep stages are determined by extracting heartbeat signals from non-invasively detected biosignals and analyzing the effect of the autonomic

nerve from the heartbeat signals. As a result, the configuration of the device implementing this method becomes complicated ~~in order to realize this method~~, the device becomes more expensive, and thus, it is difficult to routinely use the device.

[0010] Thus, the present invention aims at providing a method for determining the sleep stages, which is readily handled even by the elderly and can be routinely used without ~~giving a physical and mental load to physically or mentally burdening~~ an examinee.

[0011] Furthermore, the present invention aims at providing ~~a method for determining the sleep stages, where~~ a device realized by the method of the present invention, which is inexpensive in terms of price and maintenance costs and ~~the device is~~ readily introduced.

SUMMARY

Disclosure of the Invention

[0012] In light of the ~~actual foregoing circumstances above~~, the present invention has been made to solve, at least, the identified problems. ~~for the purpose of solving these problems, Specifically, the present invention~~ and is characterized in that sleep stages are determined by detecting signals of an examinee with a biosignal detector, calculating a signal strength variance deviation value ~~which that indicates variation deviation of the a signal strength of the signals detected by a biosignal detector, detection means and using this the signal strength variance deviation~~ value or the value of the plurality of values derived from this based on the signal strength variance deviation value as an indicator.

[0013] ~~And by making it in this way, As such, the present invention makes it is possible to readily determine sleep stages while keeping make the price and the maintenance cost inexpensive, although the sleep stages are readily determined.~~

[0014] The above-indicator value is can be characterized by the signal strength data variance deviation value of signal strength the detected data that is detected in a predetermined time period.

[0015] ~~And by making it in this way, Thus, the present invention makes it is possible to provide a simple method for determination determining sleep stages.~~

[0016] The above-indicator value is can also be characterized by a signal of a difference between the signal strength variance data deviation value of the signal strength of the detected data that is detected in the predetermined time period and a moving average of this the signal strength variance deviation value.

[0017] ~~And by making it in this way, Accordingly, the present invention makes it is~~ possible to make a method for ~~determination determining sleep stages which that~~ can be routinely used.

[0018] ~~The above indicator value is can also be characterized by a signal of the moving average that is calculated for the signal strength deviation value calculating the variance value of the signal strength detected data that is detected in the predetermined time period, and being the signal of the moving average in the predetermined time period of the variance value.~~

[0019] ~~And by making it in this way, Thus, the present invention makes it is~~ possible to make a method for ~~determination determining sleep stages which that~~ can be routinely used, and remove a high frequency component in the signals and obtain a reasonable determination result.

[0020] ~~The method is can also be characterized in that the signal strength variance deviation signal value obtained by removing abnormal values from the above signal strength variance deviation values or the value of the plurality of values derived from based on this signal strength variance deviation value is used as the indicator value.~~

[0021] ~~And by making it in this way, As such, the present invention makes it is~~ possible to remove the abnormal values caused by rolling over, etc., and obtain reasonable sleep stage determination results.

[0022] ~~The above signal strength is can be characterized by being the signal strength obtained as a reciprocal of a coefficient obtained by gain control of the signals detected by the biosignal detection means detector.~~

[0023] ~~And by making it in this way, Thus, the present invention makes it is~~ possible to obtain reasonable sleep stage determination results.

[0024] ~~The biosignal detection means detector is characterized by being a non-invasive detection means detector.~~

[0025] ~~And by making it in this way, As such, the present invention makes it is~~ possible to reduce the mental load.

[0026] ~~The above biosignal detection means detector is composed of a pressure detection tube, a pressure detection sensor and a biosignal extraction means extractor, and is characterized in that the biosignal is extracted from pressure variation detected by the pressure detection sensor.~~

[0027] ~~And by making it in this way, Accordingly, the present invention makes~~ it is possible to make the price and the maintenance cost inexpensive, ~~although while keeping~~ the handling and the measurement ~~are~~ simple.

[0028] The ~~above biosignal detection means-detector~~ is further characterized by being a heartbeat signal ~~detection means-detector~~ such as an electrocardiograph equipment and/or a pulse rate meter.

[0029] ~~And by making it in this way, As such, the present invention makes~~ it is possible to readily perform a measurement even by using typical measurement equipment.

[0030] ~~As the~~ The conventional method ~~methods~~ for examining sleep stages mentioned previously, such as the common method implementing, ~~the method for using~~ a sleep polysomnogram (PSG) ~~is common, and the methods for examining sleep stages without~~ PSG have disadvantages in that the PSG method ~~but it is difficult to use this method for~~ routine health care, ~~and the~~ The methods for simply examining sleep stages without PSG ~~have also been proposed, but there has been a problem with its introduction~~ in terms of performance and cost.

[0031] The sleep stage In the detection method of the present invention, ~~is focused~~ on the relationship between the depth of sleep in the sleep stages and the deviation in the biosignal strength. Specifically, ~~it has been a focus that the deeper sleep becomes in the sleep stages, as the depth of sleep increases in the sleep stages, the smaller the variation~~ deviation becomes in the biosignal strength, and the present invention determines the sleep stage is determined by the value of the variance deviation degree in the signal strength. In particular, only the measurement of the signal strength of the heartbeat signal has enabled the measurement of the sleep stage.

[0032] As a result, according to ~~this~~ the method of the present invention, it becomes possible to realize the measurement of sleep stages, which is readily handled and can be routinely used.

[0033] Furthermore, since the measurement method is concise, the price and the maintenance costs are inexpensive. The method of the present invention realizes a readily-introduceable-introducible device capable of determining the sleep stages.

BRIEF DESCRIPTION OF THE DRAWINGS

Brief Description of the Drawings

[0034] FIG. Fig. 1-(A) and Fig. 1(B) are show a device and a block diagram showing a flow to determine a sleep stage and a partial sectional view seen from a direction indicated by arrows, respectively, in a method for determining sleep stages of the present invention;.

[0035] FIG. Fig. 2 is shows a flowchart showing illustrating a procedure to determine a sleep stage in a first exemplary embodiment;.

[0036] FIG. Fig. 3 is shows a flowchart showing illustrating a procedure to determine a sleep stage in a second exemplary embodiment;.

[0037] FIG. Fig. 4 is shows a flowchart showing illustrating a procedure to determine a sleep stage in a third exemplary embodiment;.

[0038] FIG. Fig. 5 is shows a graph showing illustrating a relationship between the measurement results of indicator signals and thresholds; and

[0039] FIG. Fig. 6 is shows a graph comparing a sleep stage determination result in of the present embodiment invention with a result of a method using a conventional sleep polysomnogram (PSG).

DETAILED DESCRIPTION OF EMBODIMENTS

Best Modes for Carrying Out the Invention

[0040] The sleep stage In the detection method of the present invention focuses on the relationship between the deviation of, it has been a focus that the strength of biosignals during sleep and is different depending on the sleep stages. Particularly, and in particular, it has been a focus the present invention focuses on the observation that the deeper the sleep becomes in the sleep stages, the smaller the variation deviation of the strength becomes in the biosignal strength becomes.

[0041] FIG. 1-Fig. 1(A) is shows a device and a block diagram showing a process to perform for performing the method for determining sleep stages of the present invention, and FIG. 1-Fig. 1(B) is shows a partial sectional view of the device seen from a direction Xindicated by arrows. Biosignal detection means detector 1 shown in FIG. 1-Figs. 1(A) and 1(B) is a non-invasive sensor, which detects fine biosignals produced by the examinee during sleep. These The biosignals detected in by the biosignal detection means detector 1 are amplified by a signal amplification amplifier and shaper shaping means-2 so that the signals can be treated in a subsequent treatment step, and unnecessary signals such as those derived from breathing are removed through a band pass filter, etc.

[0042] The biosignal detection means-detector 1 is composed of a pressure sensor 1a and a pressure detection tube 1b, and constitutes the non-invasive biosignal detection means detector. The pressure sensor 1a is ~~the-a~~ sensor which ~~that~~ detects fine changes in pressure,. ~~A~~ ~~and-a~~ condenser microphone type for low frequency is used ~~in the present embodiment as the pressure sensor 1, but yet~~ the pressure sensor 1a is not limited thereto and may be ~~those-a~~ device having an appropriate resolution power and dynamic range.

[0043] In the condenser microphone for ~~the~~ low frequency ~~used in the present embodiment~~, a property in the low frequency range has been widely enhanced by providing a chamber behind a pressure-receiving face, whereas a common sound microphone is not considered for the low frequency region. This is suitable for detecting the fine pressure variation in the pressure detection tube 1b. The condenser microphone is excellent in measuring a fine differential pressure, has the resolution power of 0.2 Pa and the dynamic range of about 50 Pa, ~~performs has several times performance much better when compared with a typically used fine differential pressure sensor utilizing ceramics, and is suitable for detecting fine pressure added to the pressure detection tube 1b by the biosignals through the body surface. A frequency property shows a nearly flat output value between 0.1 Hz to 20 Hz and is suitable for detecting fine biosignals derived from a heartbeat and respiratory rate of the examinee.~~

[0044] ~~One-A~~ material having a proper elastic force is used for the pressure detection tube 1b so that the internal pressure undergoes a change in response to a pressure variation range of the biosignals. In order to transmit the pressure change to the pressure sensor 1a at an appropriate response speed, it is necessary to appropriately select a volume of a hollow portion in the tube. When the pressure detection tube 1b cannot simultaneously satisfy the proper elasticity and the hollow portion volume, the volume of the hollow portion can be made appropriate by loading a core rod with an appropriate thickness in the hollow portion of the pressure detection tube 1b over a whole length of the tube.

[0045] ~~Furthermore, The~~ the pressure detection tube 1b is disposed on a hard sheet 8 spread on a bed 7, an elastic cushion sheet 9 is spread thereon, and the examinee lies still on the pressure detection tube 1b. A position of the pressure detection tube 1b may be stabilized by incorporating the pressure detection tube 1b into the cushion sheet 9, etc.

[0046] As shown in Fig. 1a, In the present embodiment, two biosignal detection meansdetectors 1 are provided, ~~. The two biosignal detectors 1 are and~~ constituted to detect the biosignals regardless of the posture of the examinee during sleep by detecting the

biosignals at a chest site ~~in-by one means-detector~~ and detecting the biosignals at a hip site ~~in-the other means by the other detector~~.

[0047] The biosignals detected by the biosignal ~~detection means-detector~~ 1 are the mixed signals with various vibrations produced by the human body, and include the signals derived from heartbeat signals, respiratory signals and signals of rolling over. The respiratory signals are sometimes discontinued due to apneustic breathing during sleep. Thus, in the present invention, the biosignals in which the respiratory signals have been removed are taken out by the signal ~~amplification-amplifier~~ and ~~shaping means-shaper~~ 2 using ~~the-a filter and the a means-device~~ such as a statistical treatment device. It is obvious that ~~these~~ These signals include the extremely high-level signals ~~at extremely high levels~~ due to the rolling over.

[0048] ~~In the present embodiment, the~~ The heartbeat signals were extracted from the signals detected by the non-invasive biosignal ~~detection means-detector~~ 1, but the ~~means detector~~ is not limited thereto, and it is possible to obtain the heartbeat signals by wearing a specific heartbeat meter or detecting pulses.

[0049] An automatic gain ~~control means-controller~~ 3 is a so-called AGC circuit ~~which~~that automatically performs gain control so that the output from the signal ~~amplification-amplifier~~ and ~~shaping means-shaper~~ 2 falls within the range of the predetermined signal level. A value (coefficient) of the gain at that time is outputted to a signal strength ~~calculation means-calculator~~ 4. In the gain control, for example, the gain is set so that amplitude of the output signals becomes small when a peak value of the signals exceeds an upper limit threshold, and the gain is set so that the amplitude becomes large when the peak value is below a lower limit threshold.

[0050] The signal strength ~~calculation means-calculator~~ 4 calculates the signal strength from the coefficient of the gain control given to the biosignals ~~in-by~~ the automatic gain ~~control means-controller~~ 3. The value of the gain obtained from the above-described AGC circuit is set so as to be small when the signal size is large and so as to be large when the signal size is small. Thus, to indicate the signal strength using the value of the gain, a function ~~which~~that indicates the signal strength to be in inverse proportion to the value of the gain may be set.

[0051] For the data of the signal strength obtained ~~in-by~~ the signal strength ~~calculation means-calculator~~ 4, a standard deviation ~~which~~that indicates the ~~variation deviation~~ of the data for the predetermined time period is calculated in ~~variance deviation~~ value ~~calculation means-calculator~~ 5. That is, when at a certain time, the indicator ~~which~~that

indicates the variation deviation of the data sampled for a certain time until that time is referred to as the variance deviation value, the standard deviation is employed as the variance deviation value in the present embodiment.

[0052] In the present embodiment Further, the standard deviation was employed as the variance deviation value, which is the indicator which that indicates the variation deviation, but the variance deviation value is not limited thereto, and for example, statistical quantities such as a variance, sum of squared deviation and range may be employed.

[0053] Finally, The the sleep stage is determined in by sleep stage determination means device 6. The value of the standard deviation which that is the variance deviation value of the signal strength calculated in by the variance deviation value calculation means calculator 5 or the value derived from the standard deviation is used as an indicator signal. The threshold of the sleep stage is calculated in advance, and the sleep stage is then determined by comparing the value of the indicator signal with the value of the threshold.

[0054] FIG. Fig. 2 is a shows a flowchart showing illustrating a procedure of the first embodiment to determine the sleep stage from the biosignal strength. The procedure to determine the sleep stage by the first embodiment will be described using FIG. 2.

[0055] First, the value of the signal strength is calculated every predetermined time period, such as one second, in by the signal strength calculation means calculator 4 to output the value into the variance deviation value calculation means calculator 5 (step 210). The standard deviation of the data for 80 consecutive points at each time point is calculated to obtain the variance deviation value signal (step 220).

[0056] Abnormal values are corrected for this the variance deviation value in by the sleep stage determination means device 6 (step 230). The value of the output from the signal strength calculation means calculator 4 becomes abnormally high in some cases compared with other values of the output. For example, upon rolling over, the value of the signal strength becomes high only at that point. When the variance deviation value of the data including such a case is calculated, the resulting value becomes largely separated from the value in normal cases.

[0057] As a method for removing the abnormal value of the signal strength, it is desirable to employ a value not largely separated from the data immediately before if there is a value which that is equal to or more greater than the defined value. In the present embodiment, when When the value which that is equal to or more greater than the defined value appears, the effect of the abnormal value on the determination of the sleep stage is

excluded by replacing the value with the data within the defined values ~~which that~~ are present immediately before it.

[0058] The abnormal value of the signal strength does not frequently appear during sleep in one night, and it is also possible to omit the abnormal value depending on the number of samples used for the calculation of the standard deviation.

[0059] Then, the sleep stage is determined ~~in-by~~ the sleep stage determination ~~means-device 6 (step 240)~~. When the sleep stage is determined, a first threshold to distinguish the awake/REM sleep from the shallow non-REM sleep and a second threshold to distinguish the shallow non-REM sleep from the deep non-REM sleep are set up, and ~~it is determined from the two thresholds, it is determined which range the value of the variance deviation value signal which that indicates the variation-deviation falls into.~~

[0060] A finding that the above variance-deviation value and power density of the sympathetic nerve are in a relationship of substantial proportion has been obtained. ~~And, the The above-power density value is the value obtained by analyzing a frequency at a certain zone (about 0.04 Hz to about 0.15 Hz) of an RR interval of an R-wave in a heartbeat, and means that as the value is increased, the activity of the sympathetic nerve is facilitated, and-a causing the mind and body to reach an excited state, and thus, preventing to prevent a deep sleep state.~~

[0061] Furthermore, a finding that the above variance-deviation value and a component ratio of a δ-wave (about 0.5 Hz to about 3.5 Hz) in brain wave components (α -wave, β -wave, θ -wave and δ -wave) obtained from the brain wave are in a relationship of substantial inverse proportion has been obtained. And, the component ratio of the δ -wave is characterized by becoming large if the sleep is deepened.

[0062] ~~And, from these, the The above variance-deviation value becomes smaller in the order of the awake/REM sleep stage, the shallow non-REM sleep stage and the deep non-REM sleep stage, and the variation-deviation is larger in the awake/REM sleep stage and is smaller in the deep non-REM sleep stage. Therefore, the value of the second threshold to distinguish the shallow non-REM sleep from the deep non-REM sleep is smaller than the value of the first threshold to distinguish the awake/REM sleep from the shallow non-REM sleep.~~

[0063] As the method for obtaining the first threshold and the second threshold, it is suitable to establish the first threshold and the second threshold so that the coincidence becomes the highest compared with the determination of the sleep stages by PSG.

[0064] When the value of the variance-deviation value signal is larger than the first threshold, the stage is determined as the wake/REM sleep stage. Meanwhile, when the value of the variance-deviation value signal is smaller than the second threshold, the stage is determined as the deep non-REM sleep stage. The other cases are determined as the shallow non-REM sleep stage. The data of the continuous sleep stages are obtained by performing the above determination at each time.

[0065] FIG. Fig. 3 is the shows a flowchart showing illustrating the procedure of the second embodiment to determine the sleep stages from the biosignal strength. The second embodiment is similar to the first embodiment in that it employs the same steps 210, 220, 230 and 240, and is different from the first Example embodiment in that the moving average of the standard deviation is calculated, and the value obtained by subtracting the calculated value from the value of the standard deviation is used as the variance-deviation value signal.

[0066] For the variance-deviation value obtained by the variance-deviation value calculation means calculator 5, in the same way as in the first embodiment, the moving average value for 100 consecutive points at each time is calculated (step 231). The difference between the variance-deviation value obtained by the variance-deviation value calculation means calculator 5 and this the moving average value is used as the indicator value signal.

[0067] Then, using this the indicator value signal, the sleep stage is determined in the same way as in the first embodiment (step 240). It is also possible to select whether the correction of the abnormal value is performed or not, if necessary.

[0068] FIG. Fig. 4 is the shows a flowchart showing illustrating the procedure of the third embodiment to determine the sleep stages from the biosignal strength, and is different from the other first and second embodiments in that the moving average of the standard deviation is used as the indicator value signal.

[0069] For the variance-deviation value obtained by the variance-deviation value calculation means calculator 5, in the same way as in the first embodiment, the moving average value for 100 consecutive points at each time is calculated (step 232).

[0070] Then, using this the indicator value signal, the sleep stage is determined in the same way as in the first embodiment (step 240). It is also possible to select whether the correction of the abnormal value is performed or not, if necessary.

[0071] In the present third embodiment, this the moving average value signal is used as the indicator signal. This The third embodiment is characterized in that the high frequency component of the signals is consequently removed because of the moving average

value and the appearance of the sleep stage for a short time is ignored, whereas the first and second embodiments display the results of the fine sleep stages.

[0072] FIG. Fig. 5 is shows one example of the measurement results of the indicator signals obtained by a system implementing the method of the present invention with AGC processing, and levels of the first and second thresholds are collectively shown. Here, when the value of the indicator signal is above the first threshold (threshold 1), the stage can be determined as the awake/REM sleep stage. When the value of the signal of the difference between the variance deviation signal and the moving average value is below the second threshold (threshold 2), the stage can be determined as the deep non-REM sleep stage. When it is the level between the first threshold and the second threshold, the stage can be determined as the shallow non-REM sleep.

[0073] Fig. 6 shows The-a comparison of the above sleep stage determination results shown in Fig. 5 with the sleep stage determination results obtained by the-a conventional PSG system-is shown in FIG. 6. In this measurement comparison example, the coincidence of 86.5% is indicated, and thus the method is practically workable.

[0074] In the method for determining the sleep stages of the present invention, it becomes possible to determine the sleep stages of a great number of examinees by one device for realizing the method for determining the sleep stages because the sleep stages can be determined by only analyzing the strength of heartbeat signals. As a result, it becomes possible that the sleep stages of a great number of elderly people in a nursing home are measured for utilization of their health care.

[0075] The numbers of the data used in the calculation of the variance deviation degree and the calculation of the moving average employed in the present Example discussed embodiments are derived as one example examples, and are not limited thereto.

[0076] In the embodiments, the heartbeat signals are detected by extracting from biosignals. In this method, since the high signal strength derived from body movements such as rolling over is included in the data, it is necessary to reduce the effect of body movements, etc., by the use of correction means. However, according to the method for detecting the heartbeat signals by wearing heartbeat rate meter or pulse rate meter, no effect of the body movement is given and it is not necessary to provide correction means. But, it is necessary that the worn heartbeat rate meter or pulse rate meter is small and light enough to avoid physical and mental load.

Industrial Applicability

[0077] ~~As in the above, the~~ The method for determining the sleep stages according to the present invention is useful as the method for determining the sleep stage in which the sleep stage is determined from biosignals detected by the biosignal ~~detection means~~detector 1, and in particular, is suitable for the case of routine use because its handling is simple.